swissmedic

Public Summary SwissPAR dated 19 February 2024

Veklury® (active substance: remdesivir)

Indication extension in Switzerland: 5 April 2023

Medicinal product (antiviral agent) for the treatment of COVID-19

About the medicinal product

The medicinal product Veklury contains the active substance remdesivir. It is supplied as a powder for concentrate for solution for injection. The medicine is injected into the veins.

Veklury is an antiviral medicine (antiviral agent). It is used for the treatment of COVID-19, which is caused by coronavirus.

Veklury was already granted temporary authorisation by Swissmedic on 25 November 2020 for the treatment of patients in hospital with pneumonia who require extra oxygen.
On 24 May 2022, Veklury was also authorised for the treatment of adults with a disease caused by COVID-19 who do not require extra oxygen and who are at increased risk of progression to severe disease.

The present indication extension means that, in addition to adults, children aged 4 weeks and older with a body weight of at least 3 kg can now also be treated in hospital with Veklury. This applies to children with pneumonia caused by COVID-19 who require extra oxygen. The indication extension also means that Veklury has been authorised for adults and children with a body weight of at least 40 kg who have been infected with coronavirus and are at risk of progression to severe COVID-19. These patients do not require extra oxygen or in-patient care in hospital.

Mode of action

Veklury inhibits RNA polymerase, an enzyme which is important in the production of viral RNA (genetic material of the virus). In doing so, it prevents the virus from multiplying and helps the body to fight the infection.

Administration

Veklury, containing the active substance remdesivir, is a prescription-only medicine.

Veklury is available in a dosage strength of 100 mg.

Treatment of children aged >4 weeks with a body weight of >3kg but <40 kg: The initial dose is 5 mg/kg body weight once a day.

From the second day of treatment, the dose is 2.5 mg/kg body weight.

Treatment with Veklury lasts for at least 5 days and no longer that 10 days for children with pneumonia who require extra oxygen.

Treatment of adults and children with a body weight of >40 kg:

The initial dose is 200 mg on the first day. From the second day of treatment, the dosage is 100 mg once daily.

Treatment with Veklury lasts for at least 5 days and no longer than 10 days for patients with pneumonia who require extra oxygen.

Treatment duration is 3 days for patients who do not require extra oxygen and who are at increased risk of progression to severe disease.

Efficacy

The efficacy of Veklury was investigated in 3 different studies for the temporary authorisation in November 2020. Data from another study (GS-US-540-9012) were also taken into account for the indication extension in May 2022.

Results from the study in adults and a further study (GS-US-540-5823) were also taken into account to assess efficacy for the use of Veklury in children. This latter study investigated children who required in-patient care in hospital due to COVID-19. An improvement in the patients' state of health was demonstrated over time.

In addition, the data took into account adolescent participants from study GS-US-540-9012 in patients who did not require in-patient care in hospital and were at risk of progression to severe COVID-19. Risk factors for progression of the disease in adolescent patients were chronic lung disease, diabetes mellitus, and being overweight.

Precautions, undesirable effects, & risks

Veklury may not be used in those who are hypersensitive to the active substance or any of the excipients.

Undesirable effects of the administration of Veklury can include hypersensitivity reactions to the infusion.

Increased levels of liver enzymes were also observed in the clinical trials with Veklury. Impaired kidney function caused by the administration of Veklury can also not be ruled out. No studies have investigated possible interactions between Veklury and other medicines.

Patients should be under constant medical observation during treatment with Veklury.

All precautions, risks and other possible undesirable effects are listed in the prescribing information (Information for healthcare professionals).

Why the medicinal product has been authorised

A number of therapeutic products are currently approved for the treatment of COVID-19 in Switzerland. At present, none of these can be used in children under 12 years. There is therefore still a need for treatment options for this patient group.

The data submitted indicate that the uptake of Veklury and its effect on the body are similar in children and adults. The efficacy of Veklury in the treatment of COVID-19 in children can therefore be assumed, based on the proven efficacy in adults.

Based on these findings, Swissmedic has approved the indication extension for the medicinal product Veklury for the patient group described.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Veklury®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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